

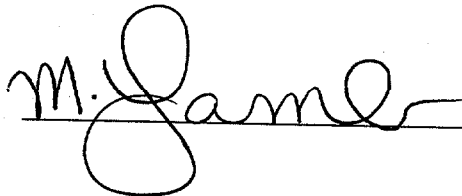
MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: 180-Day Generic Drug Exclusivity for ANDAs

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: 180-Day Generic Drug Exclusivity for ANDAs
Presented for: 1999 NAPM/GPIA/NPA/FDA Fall Technical Workshop
Date Presented: 10/18-19/99
Presented by: Cecelia M. Parise
Number of Pages: 9



Attachment

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905-0308

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1999 NAPM/GPIA/NPA/FDA Fall
Technical Workshop
October 18-19, 1999
**180-Day Generic Drug
Exclusivity for ANDAs**

Proposed Rule

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Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration*

**180-Day Generic Drug
Exclusivity**

- August 6, 1999 - Proposed Rule
Published - Federal Register
- November 4, 1999 - Comment Period
Closes

**Previous Regulation
21 CFR 314.107(c)**

- First
- Sued
- Win

Why a New Proposal?

- Previous regulation was successfully challenged in the courts

– *Mova Pharmaceutical Corp v. Shalala, 1998*

– *Granutec, Inc. v. Shalala, 1998*

What is FDA's Current Policy?

- Outlined in Guidance For Industry Published June, 1998
- "Successful defense" provision removed November 5, 1998

Who is Currently Eligible for 180-day Exclusivity?

- First Application with a PIV certification
 - Substantially Complete
 - Filed

Who is Eligible Under the Proposed Rule?

- The First Application with Paragraph IV Certification to any Patent
 - Substantially Complete Application
 - Filed

Why “Any” Patent?

- Exclusivity for each patent delays generic entry into the market and is extremely complex to administer
- A court decision on “any” patent will trigger the exclusivity period

What is a Substantially Complete Application?

- Contains all required information under the Food Drug and Cosmetic Act and the Regulations
- Contains all required bioequivalence studies

What if the Bioequivalence Study Fails?

- If study fails and needs to be repeated, firm no longer eligible for exclusivity.
- No other applicant eligible

What is the Purpose of this Policy?

- Prevents the submission of incomplete or failed bioequivalence studies in order to obtain first to file status
 - Congress and Industry expressed concerns regarding “sham” applications

What if Multiple PIV ANDAs Are Received the Same Day?

- All are eligible
- Exclusivity period shared
- The first applicant that is granted 180-day exclusivity will start the clock for all applicants

Why are Same Day Applications Eligible?

- Fairness
- Encourages the submission of quality applications

Why is FDA Proposing the Triggering Period?

- Limits the time first application blocks approval of subsequent applications
- Suggested by courts
- Brings generic drug products to market in a timely fashion

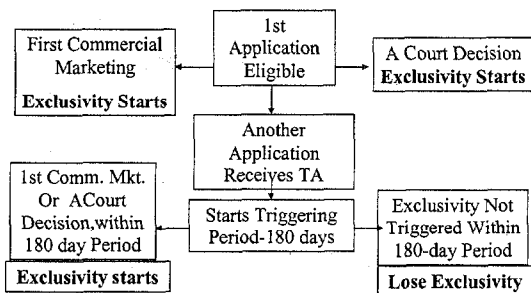
What is a Triggering Period?

- Length of time after the tentative approval of a subsequent application
- 180 days or
- 60 days -First application has final approval and there is no legal barrier to marketing
- Distinct from 180-day Exclusivity Period

What are the Exceptions?

- Triggering Period Would not Start Until:
 - 30 Month Stay has Ended
 - Injunction Prohibiting Marketing Expired
 - Statutory Timeframes for RLD Exclusivity Expired

What Can Start Exclusivity?



What is "A" Court Decision?

- Does not have to be a decision in the "first" applicant's law suit
- Can be a decision in a subsequent applicant's law suit

What if I Lose My Lawsuit?

- No longer eligible for exclusivity
- Subsequent applications may be approved

Can Exclusivity Extend Past the Patent Expiration?

No

When May Exclusivity be Waived?

- After the 180-day exclusivity period has been initiated by either first commercial marketing or a court decision

What is Relinquishment?

- The applicant relinquishes eligibility for exclusivity.
- All subsequent applications may be approved

Multiple Strength/Drug Product Exclusivity

- Each strength of a drug product is independently eligible for exclusivity

What Does FDA Expect?

- Quality Applications
- Actively pursuing approval
- Actively seeking resolution of law suits
- Timely market entry

Comments Received

- Comments were received from two entities as of October 15, 1999

Submit Your Comments to: Docket
No. 85N-0214

Dockets Management Branch (HFA-305)
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